



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/483,184 01/14/00 CRAIG

R DART1110-1

EXAMINER

HM22/0313

Gray Cary Ware & Freidenrich LLP
Suite 1600
4365 Executive Drive
San Diego CA 92121-2189

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/483,184

Applicant(s)

Craig et al

Examiner

Kar n Canella

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-81 _____ is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-81 _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-21, drawn to polynucleotide encoding Mcl-1, polynucleotides comprising the Mcl-1 gene regulatory element, vectors and host cells thereof, classified in class 536, subclasses 24.1, 23.5, 24.5, 24.31 and class 435, subclasses 320.1, 325.
 - II. Claim 22, drawn to a Mcl-1 truncated polypeptide, classified in class 514, subclass 21.
 - III. Claim 23, drawn to an antibody that interacts with an epitope of the Mcl-1 truncated polypeptide, classified in class 424, subclass 130.1.
 - IV. Claims 24-30 and 57-59, drawn to methods for expressing a nucleic acid in a cell and methods for inhibiting Mcl-1 gene expression in a cell comprising introducing the Mcl-1 gene regulatory element into the cell, classified in class 435, subclass 69.1.
 - V. Claims 31-56, 71 and 72, drawn to methods for identifying an agent which can modulate the expression of a nucleic acid operatively linked to an Mcl-1 gene regulatory element and methods for identifying an agent which induces the expression of the Mcl-1 truncated polypeptide comprising detecting a change in complex formation between the Mcl-1 gene regulatory element and the first protein, classified in class 435, subclass 4.
 - VI. Claims 60-68, drawn to methods of modulating apoptosis in a cell comprising introducing into the cell the nucleic acid encoding an Mcl-1 polypeptide, classified in class 435, subclass 69.1.

Art Unit: 1642

- VII. Claims 69 and 70, drawn to methods for identifying a cellular factor involved in splicing of the Mcl-1 transcript comprising detecting a cellular factor that binds to a polynucleotide, classified in class 436, subclass 504.
- VIII. Claims 74 and 73 in part, drawn to a method for identifying a cell expressing the Mcl-1 truncated polypeptide comprising contacting the cell with an antibody, classified in class 530, subclass 387.1.
- IX. Claims 75 and 73 in part, drawn to a method for identifying a cell expressing the Mcl-1 truncated polypeptide comprising polynucleotide hybridization, classified in class 435, subclass 6.
- X. Claims 77, and 76 and 81 in part, drawn to a method of treating a subject comprising contacting the cells of said subject with the Mcl-1 gene regulatory element, classified in class 514, subclass 44.
- XI. Claims 78-80, and 76 and 81 in part, drawn to a method of treating a subject comprising contacting the cells of said subject with a polynucleotide encoding a Mcl-1 polypeptide, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II and III are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups IV-XI differ in the method objectives, method steps and parameters and in the reagents used.

Inventions I and IV-VII are related as product and process of use. Inventions I and IX-XI are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be

Art Unit: 1642

practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group I are used for the different methods of Groups IV-VII and IX-XI, furthermore, the nucleic acids of Group I can also be used in an in vitro mutagenesis assay.

Inventions III and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used to raise an anti-idiotypic antibody..

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

3. Because of the complexity of the claims, telephonic restriction was not attempted.
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Art Unit: 1642

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

March 12, 2001

Anthony Caputa
ANTHONY CAPUTA
PATENT EXAMINER
GROUP 1642